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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,763	12/27/2005	Patrice Mauriac	270,388	8762

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EXAMINER	
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ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,763	MAURIAC ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-26 and 28-42* is/are pending in the application.

4a) Of the above claim(s) *30 and 35-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-26, 28-29, and 31-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refers to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference)

Election/Restrictions

To summarize the current election, applicant elected Group I where the active ingredient is only in the core.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 9 of U.S. Patent No. 6,620,422 in view of Chou et al. and Jain et al. (see below for citations)

Patent 6,620,422 teaches an extruded subcutaneous implant composed of PLGA and peptide where the peptide is present in particle form whose sizes vary form 1 to 60 μm (see page 3 lines 3-10; instant claims 22-24). The peptide is taught present at 20 to 40% of the implant device. The PLGA has a molecular weight between 50,000 and 150,000 and a lactic acid to glycolic acid ratio of 50:50 to 95:5. An additional skin or outer coating film is not taught present on the device.

Chou et al. teach an extruded implant that includes an outer skin (film). Such coatings are generally known to allow for added control of the release kinetics of the contained active. Further, PLGA is taught as an envisioned polymer in the core and skin (see paragraphs 10-11). In particular, the outer layer of Chou et al. is taught to minimize burst release by acting as an additional barrier between the drug/polymer matrix and the aqueous outer environment (see paragraph 35). Chou et al. teach that this PLGA coating gives a linear release profile over several months, which is an extended period of time (e.g. extended release; see paragraph 65).

Jain et al. teach that the proteins exhibit a burst release when contained in a PLGA matrix (see figures 2 and 4).

In light of these additional teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the PLGA used in the drug core of the device taught by Patent No. 6,620,422 in an outer skin as taught by

Chou et al. to give additional control of the device release kinetics, limit any initial burst that occurs, and provide a linear extended release profile. Therefore claims 22-25 are obvious over claims 1-3 and 9 of U.S. Patent No. 6,620,422 in view of Chou et al. and Jain et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 22, 25 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou et al. (previously cited) in view of Wang et al. (previously cited).

Chou et al. teach a co-extruded, implantable drug delivery device composed of a core and outer skin (film) configuration (see paragraph 8). The drug is taught present in the core (see paragraph 9). Further, PLGA is taught as an envisioned polymer in the core and skin (see paragraphs 10-11, 35 and claim 22). In addition, a drug loading level of 40% is taught (see paragraph 35). Based upon these teachings, where PLGA is specifically taught in the core and skin, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have PLGA simultaneously in both regions where the drug composed 40% of the core. Chou et al. teach that this PLGA coating gives a linear release profile over several months, which is an extended period of time (e.g. extended release) and minimizes the initial burst effect (see paragraphs 35 and 65; instant claim 22). This reference does not provide particular teachings regarding the molecular weight of the PLGA polymer or the relative proportions of lactic acid and glycolic acid.

Wang et al. teach an implant device comprised of a core and coating where the core contains poly(lactide-co-glycolide) (PLGA) and an active principle dispersed within

it, while the coating is the same PLGA used in the core (see page 1059 column 2 paragraph 4-page 1060 column 1 paragraph 2; instant claim 22). Wang et al. also teach that the PLGA used has a 75/25 ratio of lactic acid to glycolic acid and a nominal molecular weight of 100,000 (see page 1059 column 2 paragraph 4; instant claims 25 and 31-32). In addition, Wang et al., teach this configuration as being capable of generating a linear release profile (see figure 2).

Since both Chou et al. and Wang et al. teach polymeric drug cores coated with polymer, where both the core and coating polymer are the same and envisioned as PLGA, it would have been obvious to combine their teachings. It then would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the 100,000 molecular weight 75/25 PLGA taught by Wang et al. as the PLGA in the device of Chou et al. One have ordinary skill in the art would have had a reasonable expectation of success for this combination producing a limited initial release and a release profile with a linear region since Wang et al. teach that a partially linear release profile is generated from their particular polymer combinations. Applicants have not defined the time duration that corresponds to "extended release"; therefore, any duration over which a linear release profile occurs is interpreted to meet this claim limitation. In particular the multi-month release duration taught by Chou et al. meets this limitation. Thus claims 22, 25 and 31-32 are obvious over Chou et al. in view of Wang et al.

Claims 22-23 , 26, and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou et al. in view of Wang et al. as applied to claims 22, 25 and 31-32 above, and further in view of Jain et al. (previously cited) and Sakamoto et al. (previously cited).

Chou et al. in view of Wang et al. make obvious the composition of claim 22 where the inclusion of an outer coating reduces the burst release of the contained drug and linearizes the release profile. Chou et al. in view of Wang et al. do not explicitly teach the presence of hydrophilic excipients in the coating film.

Jain et al. teach that the inclusion of a hydrophilic excipient (mannitol) in a PLGA matrix imparts porosity that increases the rate of drug release from the PLGA due to added diffusion (see page 260 column 2 paragraph 1; instant claim 26). The protein myoglobin (peptide) is taught as an envisioned drug that also exhibits a burst release when contained in an uncoated PLGA matrix (see figure 4; instant claim 23). They further teach that increasing the concentration of mannitol increases the release rate. While d-mannitol is not explicitly taught, Sakamoto et al. teach this variety of mannitol as a known hydrophilic excipient in sustained release drug release preparations that increases the rate of drug release when present (see column 10 lines 38-40, table 1 and figure 7; instant claim 29). Thus d-mannitol would have been an obvious selection for the mannitol in Jain et al.

One of ordinary skill in the art would be motivated to modify the release rate of the drug contained in the composition of Chou et al. in view of Wang et al. based upon the teachings of Chou et al. (see paragraph 61). Therefore it would have been obvious

to the ordinarily skilled artisan at the time of the invention to include d-mannitol and optimize its concentration as a matter of routine experimentation. It also would have been obvious to utilize a peptide as the drug of choice since it was 1) an exemplified option in Jain et al. and 2) Chou et al. contemplate their "drug" as any agent designed to provide a local or systemic physiological of pharmacological effect when administered to mammals" (see paragraph 67). Therefore claims 22-23, 26, and 28-29 are obvious over Chou et al. in view of Wang et al., Jain et al., and Sakamoto et al.

Claims 22 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou et al. in view of Wang et al. as applied to claims 22, 25 and 31-32 above, and further in view of Fujioka et al. (previously cited).

Chou et al. in view of Wang et al. make obvious the composition of claim 22 where the inclusion of a PLGA outer coating reduces the burst release of the contained drug and linearizes the release profile. Chou et al. in view of Wang et al. do not explicitly teach the thickness of the PLGA coating.

Fujioka et al. teach a controlled release device where a zero order (linear) release profile is desired (see column 3 lines 52-56). The release rate is taught to be controlled by the presence of an outer polymer coating on a drug containing core (see column 5 lines 10-15). PLGA is en envisioned polymer for this outer layer (see column 5 lines 41-42 and 50-53). Fujioka et al. teach that the thickness of the layer is preferably from 100 μm to 1000 μm (see column 8 lines 18-24; instant claims 33-34).

Since Chou et al. in view of Wang et al. and Fujioka et al. utilize PLGA coatings in drug containing polymer cores to generate a linear drug release profile, it would have been obvious to one of ordinary skill in the art to combine their teachings. This ordinarily skilled artisan would then have found it obvious to apply the teachings regarding layer thickness in Fujioka et al. in the invention of Chou et al. in view of Wang et al. and prepare their device with a 100 μm PLGA coating. Therefore claims 22 and 33-34 are obvious over Chou et al. in view of Wang et al. and Fujioka et al.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maquin et al. (previously cited) in view of Chou et al. and Jain et al.

Maquin et al. teach an extruded subcutaneous implant composed of PLGA and peptide where the peptide is present in particle form whose sizes vary from 1 to 60 μm (see page 3 lines 3-10; instant claims 22-24). The PLGA is taught by Maquin et al. have a molecular weight from 50,000 to 150,000 and a lactic acid to glycolic acid ratio between 50:50 and 95:5 (see page 5 line 32- page 6 line 2; instant claims 22 and 25). In one example, the peptide particles are taught present at 25 wt% (see page 7 lines 11-12; instant claim 22). An additional skin or outer coating film is not taught present on the device.

Chou et al. teach an extruded implant that includes an outer skin (film). Such coatings are generally known to allow for added control of the release kinetics of the contained active. In particular, the outer layer of Chou et al. is taught to minimize burst release by acting as an additional barrier between the drug/polymer matrix and the

aqueous outer environment (see paragraph 35). The outer layer of Chou et al. also gives a release profile with at least a part that is linear (see paragraph 65).

Jain et al. teach that the proteins exhibit a burst release when contained in a PLGA matrix (see figures 2 and 4).

In light of these additional teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the PLGA used in the drug core of the device taught by Maquin et al. in an outer skin as taught by Chou et al. to give additional control of the device release kinetics and reduce any burst that occurs. Therefore claims 22-25 are obvious over Maquin et al. in view of Chou et al. and Jain et al.

Response to Arguments and Declaration

Applicants' arguments, filed July 6, 2010, have been fully considered but they are not persuasive. The amendment to the claims overcomes the rejection made under 35 USC 112, first paragraph; therefore it is hereby withdrawn.

Regarding nonstatutory obviousness-type double patenting rejection:

While the release rate of drug can be varied based upon the taught polymers selected for the core and skin, the reduction in initial burst and stabilization/linearization of the release profile is expected to occur for each combination as taught by Chou et al. Applicants suggest the interchangeability of the taught polymers of Chou et al. implied by their teachings indicates that each combination gives the same technical effect. This

is not the case. Each combination would not be expected to generate an identical rate of release and this interpretation is suggested by the teaching of Chou et al. to select various taught combinations of components to achieve the desired rate of release (see paragraphs 27, 38, and 65). However, each combination would be expected to achieve the reduced initial burst and a linear release profile subsequently. It is noted that a collection of profiles that are all linear can each have a different release rate.

Applicants additionally argue that Chou et al. does not suggest a coating with PLGA as the main component because EVA, in comparison, largely retards release of active principle. In this argument, applicants conclude from the teachings of Chou et al. that EVA is the only recommended polymer for the skin when a "very extensive retard or drug release" is desired. Chou et al. do not teach a "very extensive retard of drug release" as the sole desired endpoint of their invention and such a property is not claimed. They clearly envision the utility and desire for PLGA as the polymer skin in their exemplification and explicitly claim PLGA as the skin polymer. Moreover they present a very small number of options for the polymer included in the core and skin of the taught device. Thus on its face, each combination of skin and core polymer is obvious to try from the teachings of Chou et al. In addition, considering the examples provided that utilize PLGA as a polymer skin where in each case its presence reduced the initial burst and yielded a more stable and linear cumulative release profile, there would have been a reasonable expectation that its use on another taught polymer core would behaved similarly.

Jain et al. is referenced to demonstrate that the artisan or ordinary skill in the art would have known that the device of Patent No. 6,620,422 would have an initial burst and therefore benefited from the coating taught by Chou et al. In response to applicant's argument that Jain et al. teach a solution of PEG as an essential element of their composition, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). As a result of the initial burst release seem in all demonstrated embodiments of Jain et al., including those with PEG, it was clear the PLGA matrices of protein would benefit from the burst reducing coating of Chou et al.

According to MPEP 2144 III, "[t]he reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., In re Kahn, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)." Thus the combination of references need not be made in order to extend the release of drug, as applicants intend, but can instead be motivated for a different reason (e.g. reduction in undesirable initial burst) as the rejection suggests.

The claims and cited secondary references do not teach away from the instant invention and provide ample motivation for their combination as well as render the instant invention.

Regarding rejections under 35 USC 103(a) over Chou et al. in view of Wang et al.:

Applicants argue that Chou et al. does not suggest a coating with PLGA as the main component because EVA, in comparison, largely retards release of active principle. In this argument, applicants conclude from the teachings of Chou et al. that EVA is the only recommended polymer for the skin when a "very extensive retard or drug release" is desired. Chou et al. do not teach a "very extensive retard of drug release" as the sole desired endpoint of their invention. They clearly envision the utility and desire for PLGA as the polymer skin in their exemplification and explicit claim to PLGA as the skin polymer. Moreover they present a very small number of options for the polymer included in the core and skin of the taught device. Thus on its face, each combination of skin and core polymer is obvious to try from the teachings of Chou et al. In addition, considering the examples provided that utilize PLGA as a polymer skin where in each case its presence reduced the initial burst and yielded a more stable and linear cumulative release profile, there would have been a reasonable expectation that its use an another taught polymer core would behaved similarly. Additionally, applicants argue that the teachings of Wang et al. do not teach a partially linear release profile from a PLGA core and skin. For the CM1 and CM2 preparations that have the same PLGA polymer in the core and skin, a linear release profile is generated with little to no

initial burst (see figure 2). Although applicants argue that the duration of release measured is one day, the instant claims do not require any particular duration over which the linear release profile must be demonstrated. Applicants also argue that the hole or opening in the skin of Wang et al. was necessary to control the release of drug. Wang et al. only discussed the importance of such an opening when the coating is present at 10% to 15% on the core. In addition, Chou et al. envision embodiments where the skin partially covers its core, thereby leaving an opening like that taught in Wang et al. Moreover, the instant claims do not exclude the presence of a hole or opening in the PLGA skin. Thus the teachings of Chou et al. and Wang et al. are not inconsistent. Moreover, Wang et al. demonstrates that a PLGA polymer in both a drug core and skin were known in the art at the time of the invention and for this reason would have motivated the artisan of ordinary skill to select this combination from those suggested in Chou et al.

Although applicants argue that the teachings of Wang et al. cannot be interpreted as "extended release", such an interpretation is not necessary for this reference to be combined with Chou et al. and support the obviousness of the instant invention. Chou et al. already addressed this point in the multi-month release duration they display. In addition, applicants have not provided a limiting definition of the release duration for "extended release" therefore the breadth of 'extended release" includes any duration of release. Applicants additionally point to a teaching by Wang et al. that the polymer skinned devices were still in tact at the end of their in vitro study as an indication that the polymers were not bioerodible, as desired by Chou et al. However the polymers

utilized were PLGA which are well known in the art to be bioerodible and also taught by Chou et al. Moreover, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, the combined teachings of the cited references suggest the claimed invention to the artisan of ordinary skill.

Regarding rejections under 35 USC 103(a) over Chou et al. in view of Wang et al., Jain et al., and Sakamoto et al.:

Applicants reiterate arguments presented against Chou et al. in view of Wang et al. which were addressed above. These arguments are similarly reiterated. Applicants also argue that the incorporation of mannitol into the device of Chou et al. in view of Wang et al. would yield a faster release rate, which is the same argument provided by the rejection. However applicants suggest that such an end would not be desirable based upon the teachings of Chou et al. Paragraph 38 demonstrates that Chou et al. envisioned the incorporation of additional excipients into the core to tailor the release of the drug as desired by the artisan of ordinary skill in the art. No explicit teachings are provided by Chou et al. to exclude a release rate that is higher than that of the taught device without additional excipients.

Regarding rejections under 35 USC 103(a) over Chou et al. in view of Wang et al. and Fujioka et al.:

Applicants reiterate arguments presented against Chou et al. in view of Wang et al. which were addressed above. These arguments are similarly reiterated. In addition, applicants also that the teachings of Fujioka et al. cannot be combined with those of Chou et al. Although applicants point to a configuration of taught by Fujioka et al. that has a nondisintegrating inner layer, Fujioka et al. also teach both the inner and outer layer as biodegradable polymers. Both Chou et al. and Fujioka et al. teach a rod shaped implant with a biodegradable drug containing core and a polymer skin. In addition, both also envision some of the same polymers in these two roles, such as PLGA and polyurethanes. Therefore the teachings of these two references are able to be combined and their combined teachings render obvious the instant invention. Since both Fujioka et al. and the instant claims recite PLGA as a core and skin polymer, it is not clear that the instant invention and previously submitted declaration in any way excludes the teachings of Fujioka et al. form rendering the instant invention obvious, as applicants suggest.

Maquin et al. in view of Chou et al. and Jain et al.

Applicants reiterate arguments presented against the obviousness type double patenting rejection over U.S. Patent No. 6,620,422 in view of Chou et al. and Jain et al which were addressed above. These arguments are similarly reiterated.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Juliet C Switzer/
Primary Examiner, Art Unit 1634